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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/648,162
Filing Date: August 26, 2003
Appellant(s): IDEKER, RAYMOND E.

Laura M. Kelley
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 1/18/2008 appealing from the Office action mailed 8/23/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

This appeal involves claims 1-12, 15-18, 21-49 and 52-57. The appeal brief incorrectly listed only claims 1-3, 5-12, 15-18, 21-26, 28-40 and 42-39 as being rejected under 35 USC 103(a) as being unpatentable over "Significance of Discordant ST Alternans in Ventricular Fibrillation" by Konta ("Konta") in view of US Patent No. 6,915,156 to Christini et al. ("Christini"). In actuality, claims 1-3, 5-12, 15-18, 21-26, 28-40, 42-49 and 52-57 stand rejected as being unpatentable over Konta in view of Christini. Claims 4, 27 and 41 were correctly identified as being rejected under 35 USC 103(a) as being unpatentable over Konta and Christini in further view of US Patent No. 6,965,797 to Patore et al. ("Pastore").

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

GROUND OF REJECTION NOT ON REVIEW

The following grounds of rejection have not been withdrawn by the examiner, but they are not under review on appeal because they have not been presented for review in the appellant's brief. The rejection of claims 52-57 under 35 USC 103(a) as being unpatentable over Konta and Christini have not been withdrawn by the examiner, but they are not under review for appeal because they have not been presented for review in the appellant's brief.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Konta et al. "Significance of Discordant ST Alternans in Ventricular Fibrillation" Circulation, Vol. 82 (1990), pp. 2185-2189.

6,915,156	CHRISTINI ET AL.	7-2005
6,965,797	PASTORE ET AL.	11-2005

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-3, 5-12, 15-18, 21-26, 28-40, 42-49 and 52-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Konta et al. (*Significance of Discordant ST Alternans in Ventricular Fibrillation*, hereinafter Konta) in view of Christini et al. (US 6,915,156, hereinafter Christini). Konta discloses a method and system for detecting discordant alternans in a subject wherein 60 silver electrodes are implanted at distinct locations on the exposed pericardium of a patient in order to allow for the *chronic* detection of electrograms over a 7 minute occlusion period using a data processing system (page 2185, Col. 2). In order to identify the discordant alternans, the voltages of the ST segments from adjacent leads were compared to determine of the alternans where in phase (concordant) or out of phase (discordant) (page 2186, Col. 1, par. 2). However, Konta does not specifically disclose initiating interventional therapy in response to the identification of discordant alternans. Regardless, Konta discusses that discordant alternans are related to the development of ventricular fibrillation, which is a life-threatening condition requiring immediate treatment in a patient (page 2187, Col. 1). Furthermore, Konta does state that discordant alternans can be suppressed by treatment with the drug verapamil (page 2188, Col. 1). Therefore, despite the fact that Konta does not distinctly teach initiating therapy following detection of discordant alternans, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to deliver the drug verapamil to a patient following detection of

discordant alternans in order to prevent or treat the occurrence of ventricular fibrillation, as is suggested by Konta.

Despite utilizing implanted electrodes, Konta does not disclose using electrodes that are positioned in an internal chamber and/or vessel of the heart of the subject. Attention is directed to the secondary reference of Christini, which discloses, as an alternative to surface detection of T-wave alternans, implanting electrodes attached to leads (i.e., catheters) in the heart of the patient in order to detect electrical activity of the heart and identify alternans (see title, abstract and col. 2, lines 54-58). Furthermore, Christini defines "T-wave alternans" as equivalent to "discordant alternans" (see Col. 2, lines 3-26). Therefore, since both Konta and Christini disclose methods for chronically detecting electrical activity in the heart and then identifying alternans, it would have been obvious to one of ordinary skill in the art at the time of the applicant's to substitute one method for the other to achieve the duplicate, equal and predictable result of detecting electrical activity of the heart to identify alternans.

Regarding claim 33, Konta further discloses an external electrode for recording surface electrograms, demonstrating that the use of external electrodes to monitor cardiac electrograms is notoriously old and well known in the art.

Regarding claims 10, 11, 22-24, 47 and 48, Konta, as described above, discloses the applicant's basic invention with the exception of applying electrical stimuli to the heart in order to provide therapy to a patient in response to the detection of discordant alternans. Attention is directed to the secondary reference of Christini, which discloses applying electrical stimuli to a patient in order to control and stabilize discordant

alternans in a patient (Col. 6, lines 53-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the system/method of Konta by applying electrical stimuli to a patient since this is a known technique for stabilizing discordant alternans, as taught by Christini.

Claims 4, 27 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Konta and Christini in view of Pastore et al. (US 6,965,797, hereinafter Pastore). Konta, as described and modified above, discloses the applicant's basic invention with the exception of using alternations in an activation recovery interval (ARI) to identify discordant alternans. Attention is directed to the secondary reference of Pastore, which teaches that the activation recovery interval of heart tissue may be used to identify pulse alternans, of which discordant alternans may be included. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the method and system of Konta, as modified, by using ARI to identify discordant alternans since this is a known method of determining the existence of alternans in the heart.

(10) Response to Argument

Applicant's arguments have been fully considered but they are not persuasive. The applicant initially argues that Christini proposes the analysis of beat-pair to beat-pair differences at a single location, i.e., concordant alternans. This is simply not the case. As stated in Christini, Col. 2, lines 3-26, Christini's invention relates to repolarization alternans, which is a beat-to beat alternation in the manner by which the ventricles of the heart repolarize. Christini further explains that "action potential duration

in **different regions of the heart** first alternates concordantly and then becomes **spatially discordant**" (emphasis added). Christini then states that "repolarization alternans...is often referred to as T-wave alternans." Finally, Christini discloses that "as an **alternative to surface detection** of T-wave alternans, **repolarization alternans is detected according to the present invention from the inside surface of the heart using intracardiac electrodes**" (emphasis added). Clearly, Christini is discussing the use of a plurality of electrodes implanted inside the heart for detecting and treating repolarization alternans (i.e., discordant alternans). Despite the fact that Christini discloses that "it is, in fact, possible to detect repolarization alternans from a single spatially-localized endocardial **lead**" (emphasis added), each of the plurality of intracardiac electrodes found on that lead will inherently be placed at different locations of the heart.

Christini also discloses a methodology for stabilizing repolarization alternans (i.e., discordant alternans) (Col. 6, lines 33-35). Christini describes that if the sign between beat-pairs is consistent, an electrical stimulus is delivered to stabilize a target rhythm, and thus stabilize repolarization alternans (Col. 6, line 53-Col. 7, line 12).

The scope and content of the prior art can, therefore, be summarized as follows: Christini proposes that a single lead, with multiple intracardiac electrodes at distinct locations, can be used to detect discordant alternans, as described above. Christini uses a plurality of electrodes, such as can be connected to a pacemaker or implantable cardiac defibrillator, as an alternative to using surface detection, as described by Konta. Christini teaches the analysis and identification of discordant alternans based on a

series of heart beats detected using the electrodes (Col. 5, line 59-Col. 6, line 13). Furthermore, the base reference of Konta discloses detecting discordant alternans "based on a comparison of the electrical activity in the first and second cardiac regions", as required by independent claims 1, 18 and 38. However, Konta requires 60 electrodes that are attached to the exposed pericardium of a dog. Therefore, as directly suggested by Christini, it would have been obvious to substitute intracardiac electrodes as an alternative for the surface electrodes of Konta in order to achieve the duplicate, equal and predictable result of detecting electrical activity of the heart in order to identify discordant alternans.

In response to applicant's argument that the 60 electrodes required by Konta could not be replaced by the intracardiac electrodes described by Christini, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this case, as described above, Christini discloses using a plurality of intracardiac electrodes as an alternative to using surface electrodes, as described by Konta. One of ordinary skill in the art would thus have a reasonable expectation of success by replacing the electrodes of Konta with the electrodes of Christini.

Regarding the rejection of claims 4, 27 and 41, the appellant merely relied on the arguments presented against the combination of Konta and Christini, which have been

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addressed above. Therefore, the 35 USC 103(a) rejections of claims 1-12, 15-18, 21-49 and 52-57 are still considered proper.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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